

### R E M A R K S

Claims 1-9 are rejected as anticipated or obvious primarily over Fujita et al. (USP 5,886,014). There is also a double patenting rejection over Fujita et al.

The Examiner is citing USP 5,886,014 to reject the claims on the reasoning that the claims of the present application (thiazolidine-2,4-dione hydrochloride) and the claims of USP 5,886,014 (thiazolidine-2,4-dione and pharmaceutically acceptable salt thereof) differ only by the restriction of the present claims to the chloride salt and that the chloride salt is shown or suggested by the art. The Examiner relies on the teaching in Berge et al. [Journal of Pharmaceutical Sciences, (January 1977), Volume 66, No.1, pages 1-19] for its disclosure of hydrochloride salts as acceptable in the pharmaceutical field.

The rejection concludes that the selection and preparation of the hydrochloride salt of a known compound with the expectation of improving the parent compound's properties, would be obvious for one skilled in the art.

#### Anticipation( 35 USC 102)

Although the instant claimed hydrochloride salt is within the broad scope of Fujita et al USP 5,886,014, the portions

referred to in the anticipated rejection do not show an example of the claimed hydrochloride salt. Furthermore, the hydrochloride salt of the present claims shows a much greater effect of improving biological activity than can any expectation for such salts based on the art.

As the compounds are not shown in the art and provide unexpectedly good results, it is submitted that the invention claimed herein is a selection invention from the prior art teaching which has such different properties as to be patentably distinct from the prior art teaching. In view of the lack of an exemplification of the claimed invention and its unique properties as expected from the prior art (see discussion below with respect to obviousness rejection) withdrawal of the anticipation rejection is requested.

Obviousness (35 USC 103)

As to obviousness and double patenting rejections, it is submitted that the present invention has such unexpectedly superior properties to that expected in view of the prior art as to require a conclusion that it is a different and patentably distinct invention.

Evidence of the unexpected activity is provided in the data and detailed analysis and discussion presented in the enclosed

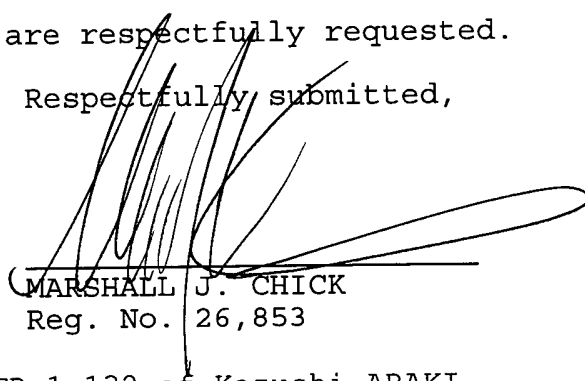
unexecuted DECLARATION. An executed version is expected to be filed shortly.

As shown by the test data and as discussed in the DECLARATION, to the extent that the art supports a conclusion that hydrochloride salts provide better results than the free compound, the expectation is two or three fold improvement. However, the actual testing provides evidence of an increase of an order of magnitude (ten-fold increase). This is highly surprising and unexpected.

In view of the above, withdrawal of the rejections and allowance of the application are respectfully requested.

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Enc. DECLARATION UNDER 37 CFR 1.132 of Kazushi ARAKI  
(Unexecuted)